

**U.S. DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
LONG ISLAND OFFICE**

1 (Proceedings commenced at 2:00 p.m.)

2 THE CLERK: Calling case civil 2020-2284, DeCostanzo
3 vs. Glaxo Smith Kline, plc.

4 Counsel, please state your appearance for the record.
5 Plaintiff goes first.

6 (No response.)

7 THE COURT: Counsel, can you state your appearances?

8 (No response.)

9 MR. SIRI: Your Honor, I'm so sorry. I was making my
10 appearance and my phone was on mute. I apologize. This Aaron
11 Siri --

12 THE COURT: I'll tell you counsel, we're having so
13 many technical issues I had no idea if I was disconnected or
14 whatever. So anyway go ahead, please.

15 MR. SIRI: My apologies. Aaron Siri on behalf of the
16 plaintiffs, along with Elizabeth Brehm from my first who's also
17 here on behalf of the plaintiffs as well. Thank you. I
18 apologize for that.

19 THE COURT: All right.

20 MR. COONEY: Your Honor, on behalf of the two
21 defendants, Gordon Cooney, Peter Nager and Natalie Georges,
22 from Morgan Lewis and Bockius.

23 THE COURT: Excellent. Anyone else?

24 (No response.)

25 THE COURT: Good. All right. We'll proceed. We're

1 here for a pre-motion conference. I've reviewed the
2 submissions of the parties appearing here today. I would also
3 just remind counsel that I reserve the right to construe the
4 letters and the arguments of counsel and the motion itself.

5 We are operating under very difficult conditions as
6 evidence by the fact -- and I don't know if this will be
7 reflected on the record, but we had trouble getting started
8 today and this is only an audio call. But we're still working
9 under pandemic conditions and people are doing the best they
10 can.

11 So I find that it's often in the interest of everyone
12 to see if we can sort of reduce these motions. Please remember
13 everyone has a right to make any motion they want. I also
14 reserve the right to just construe the motion is being made in
15 the interest of serving Rule 1 which requires, among other
16 things, efficiency and fairness.

17 So with that said let me go to defendant's counsel. I
18 have a few specific questions. If you'd like to speak generally
19 to the motions you can, but I have some specific questions if
20 you'd like me to go that way.

21 MR. COONEY: Your Honor, it's Gordon Cooney. I'm
22 happy to proceed in whatever way you prefer.

23 I think as Your Honor can see from the letter there
24 are three kind of principal overarching issues that cut across
25 the complaint. I'd be happy to kind of highlight a few of those

1 things, but I'm happy to proceed in whatever way Your Honor
2 thinks is most efficient.

3 THE COURT: Well, okay. So yes, there are three --
4 thank you for doing that and we are in agreement that there are
5 three principal grounds and I've got to talk about the
6 miscellaneous grounds in a few minutes.

7 But let me start with the principal ground. So
8 personal jurisdiction over GSK plc.

9 MR. COONEY: Yes, Your Honor.

10 THE COURT: That the complaint alleges that GSK,
11 which is defined as GSK plc and its affiliates, did all of
12 these things. At this stage am I in a position to even
13 seriously consider dismissal, or is this something that's
14 better held off till a time at which the factual
15 (indiscernible)?

16 MR. COONEY: Your Honor, I think -- I'd like to
17 address the substance of it but let's just deal with the
18 procedural issues first.

19 I think it is often the case that the complaint
20 alleges that the defendant who is named is the actor involved
21 in the case.

22 There are not sufficient or specific jurisdictional
23 facts plead in the complaint and I think the Second Circuit in
24 a number of cases, Your Honor -- I would point to the *Jazini*
25 *vs. Nissan* case, and the plaintiff has a burden and a personal

1 jurisdiction motion to come forward with a prima facie case of
2 personal jurisdiction with specific facts, not just making the
3 allegations that the defendant did the conduct involved.

4 And I think if you think about the way in which
5 personal jurisdiction has evolved recently in the Supreme
6 Court, of course, we have two concepts.

7 We have first the concept of general jurisdiction,
8 and the Supreme Court has held very squarely that general
9 jurisdiction exists only where the defendant is at home. And
10 at home is defined by the Supreme Court as being the place of
11 incorporation or the principal place of business of the
12 defendant.

13 And here I think it's undisputed that Glaxo Smith
14 Kline plc is incorporated under the laws of England and Wales
15 and has its principal place of business in the UK. And so
16 there is no question of general personal jurisdiction.

17 As to specific jurisdiction the question then becomes
18 as to whether the plaintiffs have pointed to any specific facts
19 that the particular plaintiff's claims arise from with regard
20 to contact by the defendant and the forum.

21 And so you have to look at the particular plaintiff's
22 claims and see if the plaintiff has pointed to any specific
23 contacts.

24 And what the plaintiffs point to here, Your Honor,
25 are two things. One, they say GSK's publicly traded securities

1 are listed on the New York Stock Exchange.

2 Well, number one, that's not enough for general
3 jurisdiction because as the Supreme Court has said, and as I
4 mentioned, general jurisdiction only exists where the defendant
5 has its place of incorporation or its principal place of
6 business. And simply having another presence is insufficient.

7 And with regard to specific jurisdiction, of course,
8 the claims here do not have anything to do with the issuance or
9 trading of securities. So that's not enough for specific
10 jurisdiction.

11 The most the plaintiffs point to here, Your Honor, is
12 some references on a website, the About Whooping Cough website,
13 that plaintiff does not say she ever saw, that she does not say
14 she relied on in deciding to get vaccinated in this case, and
15 in which if we submitted the declarations in support of the
16 motion to dismiss, the declarations would show that that
17 website didn't even exist until after plaintiff's vaccination
18 in this case. So that --

19 THE COURT: Let me stop you right there. So you
20 raise a very interesting point and it's secular to the peculiar
21 procedure that I've brought onto you here, which is to say
22 look, you wrote a three-page letter and should I decide it at
23 this point or should we decide it later?

24 What you're telling me is that as a 12(b)(1) motion,
25 rather than a 12(b)(6), I can consider matters outside the

1 complaint and you would submit things that say -- from GSK plc
2 that say things to the effect of we never leave Wales or
3 something akin to that.

4 So the question I could ask you is -- and I could go
5 to your adversary on this, is should your adversary get some
6 discovery on that issue before I can decide it or not?

7 MR. COONEY: Your Honor, here's where I think -- I do
8 agree that on a personal jurisdiction motion, as opposed to a
9 motion to dismiss for failure to state a claim, you can and
10 indeed, because of the way the complaints always read, often
11 you will have to go to materials outside the complaint to get
12 there.

13 And I think there is a threshold that the Second
14 Circuit has articulated for whether or not discovery is
15 appropriate. I think you can look at, as I said, the *Jazini*
16 case, 148 F.3d 181.

17 I also think there's a very helpful case from the
18 Southern District, *In re Terrorist Attacks* at 349 F.Supp 2d
19 765, that says that this can't be just a fishing expedition and
20 there to be a real prima facie showing on the part of the
21 plaintiff to get to discovery in the face of jurisdictional
22 declarations, particularly because of the purpose of personal
23 jurisdiction.

24 THE COURT: Okay. Bear in mind, of course, counsel,
25 that you have two clients and this effects -- if I'm

1 understanding it correctly, only one and in the course of
2 discovery, which tends to be broad, you know, other things can
3 come out.

4 So if, in fact, your clients you know leave Wales and
5 attend trade shows in New York City where they push handcarts
6 down the street and sell vaccines or whatever. I'm being
7 facetious, of course, but you get the idea, it's all going to
8 come out in the end. So I guess my question is the game worth
9 the candle?

10 MR. COONEY: I think it is, Your Honor. I mean this
11 is an issue of principle for plc because it is a holding
12 company and it doesn't conduct operations in the U.S. When the
13 original complaint was filed it named only plc.

14 And so we immediately called up plaintiff's counsel
15 and said plc is a holding company. It's really not involved
16 here. The right company is the U.S. affiliate, GSK LLC. We
17 think the right thing to do is to dismiss the UK holding
18 company and name. Here's the right entity to sue.

19 So we were very up front with plaintiff's counsel and
20 unfortunately plaintiff's counsel said well, no, we're not
21 going to dismiss plc, but we are going to add the LLC.

22 And so we think as a matter of policy and principal
23 that the UK holding company is at home in the UK. It does not
24 get involved in the advertising, or marketing, or distribution,
25 or sales or promotion of Boostrix and products in the U.S. and

1 the right defendant here is the LLC.

2 We brought that to plaintiff's attention and that's -
3 - we have arguments as why the claims against LLC ought to be
4 dismissed. But we do think it is very important as a matter of
5 principle.

6 THE COURT: I'm going to ask you to stop right there
7 and I'm going to go to your adversary on this one issue first.

8 So, I'm sorry. Who's speaking for plaintiff today?

9 MR. SIRI: Aaron Siri, Your Honor.

10 THE COURT: All right. Sir, so let me ask you this.
11 You heard the discussion we just had and I'll ask you the same
12 question. Is the game worth the candle? I mean, if you tell
13 me you already the evidence and you put it in the complaint,
14 then we've got a different story.

15 At the end of the day, since you have another
16 corporation involved in the case as a defendant does it matter?
17 Do you want to spend a lot of resources on this question, I
18 guess is the question.

19 MR. SIRI: Yes, well, with regard -- well, I'm start
20 at the end. I mean, with regard to whether or not we want to
21 spend resources on it, defendant's counsel did reach out, as he
22 indicated and advised, that he believes the correct entity is
23 the LLC entity, not the plc entity.

24 And what we advised defense counsel at that time was
25 -- we said look, there's two issues. One is the crux of the

1 complaint here is a false advertising, that there is a campaign
2 that was launched by GSK regarding their product that was
3 intended to create a level of fear regarding pertussis and to
4 persuade folks to get GSK's product.

5 That campaign that they -- they bought, they created,
6 they chose to put advertisements on TV and on the internet. It
7 lives in the form of a website and a commercial.

8 When we went and looked at that website and
9 commercial, the only identifiable entity that we could find was
10 GSK plc. There is a link, as we allege in our complaint. This
11 is all in the complaint.

12 As we allege in the complaint there's a link on the
13 page for the website which also includes the commercial on the
14 website that is entitled interest based ads. And it explicitly
15 defines what GSK means as used in all of their (indiscernible)
16 ads and all of their advertising. And it says GSK plc and
17 affiliates.

18 And so we knew that at the least is GSK plc, you
19 know, is the entity that is -- when all of these ads use the
20 term GSK it means GSK plc and it might mean other entities, but
21 at the least it means GSK plc.

22 I've asked defense counsel to provide additional
23 explanation as to why their actual advertising material says
24 it's GSK plc and the only explanation is that well, you know,
25 it says and its affiliates. Well, that's right. It says and

1 its affiliates. It doesn't say or its affiliates maybe would
2 have give them (indiscernible) but -- so that is the only
3 answer that -- hence it's the only entity that we sued when we
4 brought the action.

5 Had we been able to identify the LLC entity as
6 connected to this advertisement, we certainly would have sued
7 them.

8 Second point is that we also asked for an
9 understanding of the financial position situation of this LLC
10 entity. And it's a class action.

11 Obviously, we have duties on behalf of the punitive
12 class and we want to make sure that the LLC entity, which they
13 are very insistent on wanting to be the only defendants here,
14 have the financial resources to pay.

15 You know, one of the things we found was that
16 recently this entity LLC had to pay hundreds of millions of
17 dollars in damages because regulators found improper conduct
18 regarding one of the products.

19 I don't know what financial state that has left that
20 entity in. I have asked for visibility from defense counsel as
21 to the financial state of that entity, and we have not gotten,
22 you know, the visibility that we think would permit us to make
23 an appropriate decision to say well, you know, what, this LLC
24 has so much money that we don't have to worry about it. You
25 can drop plc.

1 THE COURT: Okay.

2 MR. SIRI: I think it would be imprudent and it
3 certainly would be a problem --

4 THE COURT: Counsel, I get it.

5 MR. SIRI: Yeah. Can I make two more points, Your
6 Honor, very quickly to respond?

7 THE COURT: No. No. Not unless you want to snatch
8 defeat from the jaws of victory. I'm good. I think you're
9 entitled to discovery on this point. So I'm denying the motion
10 without prejudice (indiscernible) renewal at a later point
11 after there's discovery.

12 I find that the allegation that the plc entity, if I
13 have that right, was sufficiently involved in this and on the
14 website which -- and there can be arguments. And I'm not
15 foreclosing this forever, but I believe the plaintiff at a
16 minimum is entitled to discovery at this early phase.

17 MR. COONEY: Your Honor, can I just make --

18 THE COURT: You make seven points, counsel, but you
19 know, we are where we are.

20 MR. COONEY: Your Honor, if I could just make one
21 point on this and that is the website that they're referring to
22 all it says is references to GSK, we, us and are, are
23 references to Glaxo Smith Kline plc and it's affiliates.
24 That's all it says.

25 More importantly, the website didn't even exist when

1 the plaintiff was vaccinated. The plaintiff's claims can't
2 arise in this case from the website. The plaintiff only points
3 to the commercial, the TV ad. There is nothing in the TV ad
4 that refers to plc. There's nothing in the complaint that says
5 --

6 THE COURT: Here's where you and I are in violent
7 agreement. This is the sort of thing that should be worked out
8 among counsel. It's plaintiff's job to cast a wide net. It's
9 defendant's job to try to narrow that net but you say to me you
10 reach out and try to work it out. I understand. That's great.

11 On the other hand, counsel represents to me that they
12 want to make sure that the affiliate has the financial
13 wherewithal to withstand the judgment. It's probably work you
14 don't want to engage in right now and I understand that.

15 So right now I'm leaving the plc entity in. You
16 might prove to me to complete conclusion at some point that plc
17 has not place in the case, and at that point I'll dismiss it,
18 but they have a right to look further, at least until we can
19 figure out (indiscernible).

20 MR. COONEY: Your Honor, the one other thing I would
21 say is we did provide plaintiff with significant information
22 also the financial heft and magnitude of LLC. We heard nothing
23 about some large judgment or any concern about that.

24 I would hope that a minimum the discovery that would
25 be directed again plc at this point would be on the

1 jurisdictional issue. We'll respond on behalf of LLC with
2 regard to any merits discovery, if we get past the 12(b)(6)
3 point. But obviously the purpose of personal jurisdiction is
4 to avoid burden on a defendant who is not properly before the
5 court.

6 And so I would hope that at least discovery would be
7 jurisdictional discovery and it would be tailored, as the
8 Second Circuit has suggested in the cases that I've talked
9 about.

10 THE COURT: I understand. I'm not limiting today.
11 But if it gets to be burdensome, you will let me know and
12 you'll let the magistrate judge and we'll see what we can do.
13 All right. So we'll take it from there.

14 Let's go onto your next point. Please, what is the
15 next argument you would like to talk about?

16 MR. COONEY: So, Your Honor, the next argument really
17 has to do with the doctrine of preemption and primary
18 jurisdiction and plaintiff's claims of injury.

19 From the face of the original amended complaints,
20 Your Honor, it appeared that the plaintiff was making a claim
21 for physical injury.

22 What the plaintiff asserted in the claim was that her
23 vaccine caused her to develop a "defective form of immunity"
24 and that according to plaintiff what that meant was that she
25 would get vaccinated. She could contract pertussis, not

1 develop any symptoms but be in a position to unknowingly
2 transmit that pertussis to others. That was the allegation of
3 the complaint.

4 Any such claims for that kind of injury are preempted
5 by the Federal Vaccine Act that we identified in the --

6 THE COURT: Wait, wait. Hold on, hold on. I thought
7 -- your suggestion to me was that the Vaccine Act preempted
8 claims for physical injury. Yeah?

9 MR. COONEY: They preempt claims for physical injury
10 and that probably also includes emotional injury, Your Honor.
11 So physical injury is -- the definition in the act is broad. I
12 would agree it doesn't include economic injury.

13 THE COURT: So I think it is a --

14 MR. COONEY: It is a broad definition.

15 THE COURT: Unless I'm misreading it I think
16 plaintiff has conceded that there's no physical, or I would go
17 as far as to say apparently emotional injury, that it's only
18 economic. If that's the case, then this argument goes away,
19 yes?

20 MR. COONEY: I would agree that if there is no claim
21 for real emotional injury and there is no claim for physical
22 injury that the Vaccine Act would not preempt or require the
23 plaintiff to present that claim.

24 I will note that it is -- there is nothing that would
25 have prevented plaintiff from seeking compensation under the

1 Act and we believe that given the claims that had been asserted
2 that was the appropriate step.

3 But where does that leave us? It leaves us with two
4 things to discuss. One is whether there is a legally
5 cognizable injury, Your Honor, and it also leaves us in a
6 discussion about the doctrine of primary jurisdiction with
7 regard to the remaining --

8 THE COURT: Well, let's go back to that in a second.
9 Let me just confirm with plaintiff's counsel -- I just want to
10 make sure I'm misreading it. Plaintiff's counsel, is it fair
11 to say at this point we have no -- from the plaintiff no claim
12 for physical or emotional injury. Am I right about that?

13 MR. SIRI: Yes. We don't have any claim for personal
14 injury in our complaint.

15 THE COURT: As well -- right. And that would include
16 physical and emotional, yes?

17 MR. SIRI: Right. Our claims are for consumer fraud,
18 warrantee of fraud, unjust enrichment and negligent
19 misrepresentation.

20 THE COURT: Okay. And just forgive me. I thought I
21 came across this, but your client was -- got this through an
22 insurance -- it was a co-pay. I mean, is there actual dollars
23 out of the pockets that we can identify at this point?

24 MR. SIRI: What we alleged in the complaint is that
25 the clients pay for the product directly or indirectly. We

1 allege that a few times contrary to what the defendants put in
2 their letter.

3 We believe that there wasn't a co-pay, that it was
4 covered by insurance. And so there would have been an indirect
5 payment for the product by the plaintiff.

6 THE COURT: Interesting. Okay. Great.

7 Back to defendant's counsel. So I want to make it
8 clear on the record that there is no claim for physical and
9 emotional injuries, as counsel just concedes.

10 So believe that the preemption under the National
11 Childhood Vaccine Act argument, or failure to exhaust, goes
12 away. Fair?

13 MR. COONEY: I think that's fair, Your Honor, based
14 on that understanding.

15 THE COURT: Look, we're making progress.

16 MR. COONEY: I agree.

17 THE COURT: You should feel good about that.

18 MR. COONEY: I do, Your Honor.

19 THE COURT: So now you want to tell me about the FDA
20 primary jurisdiction -- CDC primary jurisdiction issue, yeah?

21 MR. COONEY: I mean, maybe while we're just in the
22 area of talking about injury, I think what that leaves, Your
23 Honor, is that there is no claim for direct economic loss here,
24 Your Honor. The plaintiff is not out of pocket and I think
25 that's now clear.

1 And what the plaintiff's economic claim is is that
2 she needed to travel to her local pharmacy and we cite cases in
3 our letter that that is not legal injury under New York law and
4 she's made --

5 THE COURT: Well, hold on. Hold on. Back up a
6 second.

7 Wouldn't the payment of the insurance premiums count
8 or no?

9 MR. COONEY: I don't think so, Your Honor. There's
10 no suggestion and there's no basis to say that there was any
11 change in her premiums. That she paid any more or was affected
12 in any way in terms of her premiums as a result of the insurer
13 reimbursing for pertussis. And, in fact, the insurers often
14 encourage this kind of behavior because it keeps down costs.
15 That's often why there is no co-pay.

16 So there is no basis in this complaint and based on
17 what we've heard to conclude that there's any economic injury
18 that the plaintiff has incurred in this case.

19 THE COURT: Okay. Let me think about that a little.

20 But you don't -- do you have cases specific to that
21 issue that they sort of -- incidental economic harm is not
22 sufficient to sustain the action?

23 MR. COONEY: We certainly cited a case, Your Honor,
24 that cases -- that claims of inconvenience like travel to get
25 the product or whatever are not legal injury. I think we cited

1 one such case in our letter.

2 If the court would like some additional supplemental
3 briefing on that issue, we'd be happy to do it. But there is
4 no basis to conclude that this plaintiff has suffered any
5 economic injury at all as a result of her vaccination with
6 Boostrix.

7 THE COURT: So then assuming every allegation in the
8 complaint is true what you're telling me then is it's the
9 insurer that has to come as a plaintiff, yeah?

10 MR. COONEY: If there is a claim for economic injury,
11 it would to the insurer. And, of course, the insurer would
12 have to conclude independently that -- whether or not it agrees
13 with the public policy that this particular plaintiff is
14 articulating, which seems to be more of a anti-vaccination
15 public policy. The insurer might well disagree with that, as
16 does CDC. So --

17 MR. SIRI: I don't believe that plaintiff is bringing
18 a case to try and stop anybody from getting vaccine. I don't
19 think there's anything anti-vaccine about it.

20 I believe the claim is very clear, the defendants
21 here lied to the public that getting this vaccine will prevent
22 the person who gets it from becoming infected and transmitting
23 pertussis.

24 And, in fact, the reality is what this product does
25 is it does reduce the symptoms of pertussis. It does stop you

1 from getting the disease, but it renders you still capable of
2 becoming infected with pertussis and transmitting it.

3 And so when they were running a national TV campaign
4 depicting grandmas and plaintiff as wolves with sharp teeth,
5 reflecting in the eyes of little babies to make these parents,
6 these grandparents fear that if they don't get plaintiff's
7 product they are endangering -- they are apparently like wolves
8 who are going to I guess injure their grandkids and other
9 children.

10 They created that fear to sell their product and they
11 won awards, as we alleged in our complaint, for that
12 advertising campaign because it did increase sales of their
13 product.

14 But the reality turned out that actually that product
15 rendered them more likely to transmit pertussis to their
16 grandkids and other children because while it reduced symptoms,
17 it didn't prevent infections and transmission.

18 I don't know what about that is anti -- that's a
19 straight claim of lying to the public. And, you know --

20 THE COURT: So to summarize -- to summarize, counsel,
21 you're saying you're not against vaccines. You're just against
22 vaccines that don't work. Is that the allegation?

23 MR. SIRI: I think we're attorneys alleging that
24 defendants have lied about the -- how this product works. That
25 it reduces symptoms so those who receive the product so that

1 they won't get pertussis disease, that there's a product that
2 does that and apparently it is theirs. But it doesn't do the
3 rest.

4 In terms of -- the point is that I don't believe -- I
5 think that that was just intended as a slight. That's not
6 representative of -- they're trying to deflect from the fact
7 that their clients basically lied to the public about what this
8 product will do. And in fact --

9 THE COURT: Okay. Counsel, while I have you -- hold
10 on. Hold on. Because since you've volunteered to help, I get
11 to ask more questions.

12 How do you articulate a loss in this case?

13 MR. SIRI: How do I articulate a what? I'm sorry.

14 THE COURT: A loss, an economic loss.

15 MR. SIRI: Well, there is the indirect economics.
16 The plaintiff does have to pay for insurance, as Your Honor
17 pointed out, as obviously insurance then pays for the product.

18 Separately the entire purpose of this advertising
19 campaign that they engaged in in New York and across the
20 country was to create fear that by not getting their product
21 they could be a danger to children.

22 THE COURT: Well, but that doesn't (indiscernible).

23 MR. SIRI: There are cases that support not economic
24 loss, but there are cases that support that damages can be
25 supported by increasing fear.

1 And here, in fact, that's what's happened which is
2 upon learning how this product -- what this product actually
3 does that, in fact, it rendered those who received it more
4 likely to transmit pertussis to grandkids and children because
5 while it reduced the person who its symptoms, they could still
6 transmit it, meaning they won't even know they're sick when
7 they're infected and transmitting pertussis.

8 And so it only has now served by getting
9 (indiscernible) to increase the very fear that their
10 advertising created, and that is a harm that is recognized as a
11 basis of damages as well.

12 THE COURT: All right. Okay. Let me go back to
13 plaintiff's counsel.

14 MR. COONEY: Your Honor --

15 THE COURT: Go ahead.

16 MR. COONEY: -- if I could address each of those
17 things. So first --

18 THE COURT: Actually, you don't need to. Hold on.
19 Hold on. You don't need to because I'm (indiscernible) on
20 that. It's too much to shoot from the hip on that.

21 MR. COONEY: Understood.

22 THE COURT: Let's go back to the primary jurisdiction
23 CDC, FDA issue.

24 MR. COONEY: Okay. So, Your Honor, I think the key
25 thing to remember here as part of the primary jurisdiction

1 point is we have an FDA approved Tdap vaccine and it's also
2 undisputed, Your Honor, that the Centers for Disease Control
3 specifically encourage the public to get the vaccine, including
4 to protect from adults transmitting to infants.

5 The crux of the plan's allegation here is that GSK's
6 advertisement for Boostrix should have stated the exact
7 opposite.

8 Plaintiff's claims -- all of plaintiff's claims are
9 premised upon the contention that GSK should have said to those
10 public that Boostrix creates a defective form of immunity and
11 GSK should have said that it does not protect from transmitting
12 pertussis from adults to children when CDC says the exact
13 opposite. Its guidance to the public is get the vaccine and it
14 helps to transmit -- or to prevent the transmission of
15 pertussis from adults to children.

16 And the plaintiffs rely on some cherry picked
17 allegations from three studies that make their claim, but
18 putting that aside this case directly implicates both the FDA
19 approval but more importantly CDC's expertise around what is in
20 the best interest of public health.

21 Your Honor, these claims threaten the consistency of
22 message from CDC concerning the efficacy of Tdap vaccines and
23 these issues, the issues about what the public messaging should
24 be, GSK's public messaging about these vaccines was completely
25 in congruence with what CDC was saying.

1 And what the plaintiffs are saying is we should have
2 affirmatively (indiscernible) something that's completely
3 contrary to the Center for Disease Control's guidance. And
4 those issues -- this issue, consistency of guidance from CDC, I
5 think we see lots of challenges associated with when there are
6 different mixed messages out there.

7 The question of what message should be given to the
8 public regarding the efficacy of these Tdap vaccines ought to
9 be resolved by CDC, not by a jury under state law. And
10 particularly with a plaintiff who had suffered no injury and if
11 they had an injury could have brought it in front of the no-
12 fault program.

13 And so these issues -- I do think there is a big of a
14 relationship between the injury and the primary jurisdiction
15 doctrine. We have a plaintiff here with no injury. And the
16 crux of the complaint is at odds with CDC guidance.

17 MR. SIRI: May I respond?

18 THE COURT: Please.

19 MR. SIRI: Thank you. Well, first is the argument
20 that we -- the plaintiff is stating that GSK's advertisement
21 should have informed the public that their product doesn't work
22 to prevent infections (indiscernible) is a straw man argument.
23 Nowhere in the complaint nor is that the argument that
24 plaintiff's making. We're not arguing that they should have
25 said anything.

1 The argument that plaintiff is making is that the
2 defendants should have done nothing. They could have chosen to
3 not run their advertising campaign. They didn't need to go to
4 the public and tell them that their product doesn't work right.
5 They could have sat on their hands and done nothing.

6 They chose affirmatively to create an advertising
7 campaign, put it on American television sets, target New
8 Yorkers, put an entire website up around that campaign to
9 provide the ability to find thousands of providers in New York
10 where you can their Boostrix products, and like I said won
11 awards for that campaign for how effective it was. That was
12 their --

13 THE COURT: So I'm what I'm confused about counsel
14 today is I'm presuming that there was FDA approval to
15 distribute this product, yeah?

16 MR. SIRI: There was FDA approval. But we're not
17 challenging --

18 THE COURT: So hold on. Hold on. Stop, stop, stop.

19 MR. SIRI: I was getting to that. I was getting to
20 that.

21 THE COURT: Is there a suggestion that defendants
22 knew something that the FDA didn't? In other words, what --
23 where's the disconnect that said it really doesn't fall within
24 the area of administrative competence that (indiscernible) talk
25 about.

1 MR. SIRI: Absolutely, Your Honor

2 So this lawsuit -- and we cited case law for this.
3 This lawsuit in no way challenges the FDA's licensure of this
4 product or the CDC's recommendations regarding this product.
5 There's nothing in this lawsuit that would prevent the FDA from
6 continuing the licensure or the CDC to continue to recommend
7 the product. Nothing at all. We're not challenging the
8 licensure.

9 The one case that defendants cite to support their
10 position, *Doe v. Merck*, was an -- the HHS, the Department of
11 Health and Human Services, which is the parent department to
12 the FDA, was a defendant and the plaintiff there was seeking to
13 actually have Merck's licensure for a different vaccine
14 cancelled by the FDA. That's okay. In that situation, sure
15 preemption makes sense.

16 But in this case we're not challenging anything with
17 regards to the FDA's licensure or the CDC's recommendations
18 regarding these products. We are simply challenging the
19 defendant's choice to create and run a false advertising
20 campaign.

21 Incidentally, and I don't think this matters,
22 frankly, but incidentally the licensure of the product relates
23 to preventing disease, meaning preventing symptoms. This
24 product by all accounts does to that. It prevents disease.

25 THE COURT: Okay. So you're saying that it construed

1 the nature of the approval. Fair?

2 MR. SIRI: Well, the --if you pull up the package
3 insert for the Boostrix product it has an indicated use. The
4 indicated use doesn't include preventing infection and
5 transmission. It's about preventing pertussis and disease.
6 But, again, I don't think that that's relevant because we're
7 not challenging in any -- even if they did include that, which
8 it doesn't, we're not challenging that, the FDA's licensure or
9 any of that.

10 The other thing I'll point out is that the defendant
11 here throws out the plaintiffs put some cherry picked studies
12 in their complaint. These are not cherry picked studies, one
13 of those by the FDA itself.

14 Another one has co-authored that are GSK consultants
15 and is probably the seminal study on this issue published just
16 last year. To call them cherry picked studies is a little
17 rich. I'm sorry, Your Honor --

18 THE COURT: You know what, counsel, let me just stop
19 you there.

20 Counsel, I have a feeling that this case is going to
21 go on for a long time. And I don't (indiscernible) attack back
22 and forth. I don't care. It doesn't affect me. It just wastes
23 time. So just get to the points that you want to cover.

24 MR. SIRI: I'll make a last substantive point and
25 it's this. With regards to any claims about what the CDC or

1 FDA say about this product are outside of the four corners of
2 the complaint as well, and I don't think are appropriate to the
3 motion to dismiss at this time.

4 THE COURT: Okay.

5 MR. COONEY: Your Honor, if I could just make four
6 points. If I can just make four points.

7 THE COURT: Sure.

8 MR. COONEY: First, I think it's clear that on a
9 primary jurisdiction motion it is entirely appropriate for the
10 court to look outside the face of the complaint.

11 Second, what the plaintiffs say is misleading about
12 the ads. And it's clear from the complaint is that GSK failed
13 to disclose what plaintiff's claim, it is that Boostrix is not
14 effective and that GSK should have specifically said -- that's
15 the claim, GSK should have specifically said that it's not
16 effective in transmitting -- at preventing the transmission of
17 pertussis from adults to children. Both of those things are
18 completely contrary to the CDC guidance.

19 Third point, FDA's approval of a vaccine and a
20 medicine constitutes a finding as to both efficacy and safety
21 and then finally when you look at the injury, if this sort of
22 case where a plaintiff had suffered a real and meaningful
23 injury and the court is trying to weigh the value of proceeding
24 in court against the risks associated with interfering with
25 agency expertise, we've got a plaintiff we who think has no

1 legal injury.

2 THE COURT: But I don't think that matters.

3 MR. COONEY: And against that. --

4 THE COURT: Counsel. Counsel, counsel, counsel, hold
5 on. I don't think that matters.

6 In other words, if the plaintiff has no legal injury,
7 then the case may get dismissed on that ground. If the
8 plaintiff -- if the only injury alleged is the needle prick
9 from the shot or whatever it is, or was something horrendous
10 the legal analysis is the same. Right? Either it's within the
11 FDA's jurisdiction or it's not unless I'm missing some part of
12 this test.

13 MR. COONEY: No, I don't disagree with Your Honor. I
14 do agree that -- I think the lack of legal injury issue is
15 dispositive of the whole case.

16 The point I'm simply making is that this case
17 presents a significant risk in terms of interfering with CDC's
18 guidance because at its heart, although it's about advertising,
19 what the plaintiff says is wrong about the ads is that we
20 didn't say that which is inconsistent with CDC's guidance. And
21 that is the kind of question that needs to be resolved by
22 (indiscernible).

23 THE COURT: But isn't that the point then. Isn't that
24 sort of the interesting aspect of this? In other words, if
25 they're not attacking the approval (indiscernible) but saying

1 that you advertised this for what I think is called in other
2 circumstances an off label use, right? You know, it's approved
3 because you know, if you get this, you actually won't cough
4 when you get the whopping cough but you'll still have whooping
5 cough.

6 And then you take a -- you know, print ad that says
7 guess what? Use our vaccine and you won't get whooping cough.
8 That's a difference, right? Isn't that (indiscernible).

9 MR. COONEY: I don't think the off label analogy is
10 appropriate here though, Your Honor, because here unlike an off
11 label case where you don't have a governmental entity saying
12 use this product for X, right? In an off label case the
13 approved indication is A and you don't have the government
14 saying use the product for X.

15 Here you have CDC telling people we want people to go
16 out and get his vaccine. So the CDC wants to encourage people
17 to get the vaccine. That's consistent with the concept of a
18 manufacturer advertising.

19 And the only thing that the plaintiff says is
20 misleading about the ads is the failure to disclose that which
21 CDC says the exactly opposite. That it's efficacious. That
22 the CDC wants people to get the vaccine and that it's a good
23 idea for adults to get the vaccine to try to minimize the
24 transmission of the disease to children.

25 So what's I think fundamentally different from some

1 of the other preemption cases and the off label cases is you
2 don't have a governmental entity actually encouraging the
3 message.

4 And that's where there's I think a very significant
5 distinction between this case and what CDC is saying, and the
6 complete alignment of the advertising with CDC and the complete
7 disconnect between what plaintiffs say we should have said and
8 what CDC wants as the public message.

9 MR. SIRI: Your Honor, I think it's misleading to say
10 that what we're trying to say is they should have sent a
11 certain message. Plaintiff's position is that they shouldn't
12 have made a false messaging.

13 To that point, since defendant is talking about facts
14 outside of the complaint they have I think in line with
15 understanding that they shouldn't make false -- you know, those
16 kinds of false statements, have taken of the entire big bad
17 wolf commercial and advertisements from their website now.

18 And I think that that's reflective of our point,
19 which is not that they should affirmatively state it doesn't
20 work, but they shouldn't be affirmatively stating it does do
21 certain things that it doesn't, as reflected by the fact they
22 appear to now no longer make those statements on the big, bad
23 cough website.

24 The other thing, and this other point, and it's
25 really relevant, which is the FDA and CDC didn't provide

1 approval for these ads. These aren't like a package insert
2 that are approved by the FDA.

3 These are advertisements that the GSK made of their
4 own accord that they chose to play to consumers around the
5 country. These are not ads that are approved by federal health
6 agencies and there's no -- again, nothing in this lawsuit is
7 seeking to disrupt the licensure of these products or the CDC's
8 recommendations for these products.

9 THE COURT: Okay. I think I have what I need on that
10 point.

11 I think that leaves us then with what I'll call the
12 bucket point, which means the bucket of additional state law
13 grounds for dismissal.

14 Let me start with defendant's counsel. Do you think
15 that given the limitations that I've given you in terms of a
16 three-page letter and so forth that you've had adequate room to
17 sort of flesh those out, because I'm not sure that you do.

18 MR. COONEY: Yeah, I don't know that we have, Your
19 Honor. And I think we obviously prioritized the issues that we
20 think are overarching and I continue to think that the no
21 injury and primary jurisdiction arguments are dispositive. And
22 it may be that the no injury argument alone is dispositive
23 here.

24 You know, the bucket for arguments I think are
25 important. They would shape the contours of the case. If the

1 case were to proceed, it would be helpful to know what claims
2 are in or not in for purposes of class certification and I
3 think a class would be very difficult here given the injury
4 claims.

5 But I do think it would be helpful to perhaps devote
6 a little attention to those arguments, in addition to the no
7 injury point that you've asked for some further briefing on.

8 THE COURT: Plaintiff's counsel, are you on board
9 with that?

10 (No response.)

11 THE COURT: I'm sorry. Maybe I -- do you guys think
12 -- plaintiff's counsel, do you agree?

13 MR. SIRI: I'm sorry. I did again. I'm so sorry. I'm
14 talking to myself. I apologize.

15 THE COURT: I'm sure you made a great point. I'm
16 sorry I missed it.

17 MR. SIRI: Well, I wish I could say I did. I really
18 didn't. I just said -- if I'm on board with -- I apologize.
19 You mean, a briefing schedule for the defendant's motion to
20 dismiss?

21 THE COURT: Yeah, for the miscellaneous grounds to
22 dismiss, yeah?

23 MR. SIRI: Sure. Whatever Your Honor will find most
24 helpful.

25 THE COURT: No, I'm just saying I don't think there's

1 -- it was hard for me to sort of flesh out all of them because
2 there was this kind of one paragraph devoted to a bunch of
3 arguments. So I thought perhaps you wanted to go into a little
4 more detail on --

5 MR. SIRI: Sure. When you say briefing, Your Honor,
6 do you mean like doing a fulsome motion to -- fulsome briefing.
7 Not additional letter --

8 THE COURT: A brief devoted to those matters that I
9 can't decide today, yeah?

10 MR. SIRI: Sure. Yes.

11 THE COURT: You sound troubled or confused and I
12 don't want to (indiscernible) at that.

13 What I'm (indiscernible) - there's an implication of
14 a bunch of other grounds but I don't really know what they are.
15 We can go through this process again and I can you both
16 (indiscernible) letters on those but I think since I'm going to
17 have you submit a brief anyway maybe I should just have you
18 cover all the state law grounds and the other issues that you
19 want to (indiscernible). Makes sense?

20 MR. SIRI: Makes sense.

21 MR. COONEY: Yes, Your Honor.

22 THE COURT: Okay. Good all right.

23 In that case I am ready to wrap this up. So let me
24 start off by saying counsel has done a fine job under very
25 difficult circumstances and we're doing our best but I think

1 we've got some good work done today.

2 So what I will start off by saying is -- so as set
3 forth in Rule 2(e)(1) of my individual rules, the court
4 reserves the discretion to construe the premotion letters,
5 along with counsel's argument, as the motion itself. As noted
6 in that rule, the procedure's been upheld by the Second
7 Circuit.

8 Under appropriate circumstances I find the exercise
9 of such discretion is rendered more appropriate by the
10 existence of the individual rule, which effectively puts
11 counsel on notice of this possibility, as well as the fact that
12 we are still in the throws of a pandemic, which makes things
13 difficult.

14 In any event, to the extent that these are 12(b)(6)
15 motions, and more on that in a second, the motion decided under
16 the well established standard review for Rule 12 motions, as
17 discussed in numerous cases, and I won't burden the record with
18 all of that. But suffice it to say I'm incorporating by
19 reference the standards for 12(b)(1) and 12(b)(6)
20 determinations.

21 But under 12(b)(6), at least the court is
22 (indiscernible) to decide, assuming the allegations to be true
23 for the purposes of the motion, whether there are sufficient
24 facts to determine (indiscernible) on its face.

25 So based on a review of the complaint and after

1 considering the arguments of counsel, which were well done, I
2 am going to grant some of the motions in part and deal with
3 others in different ways as follows.

4 On the question of personal jurisdiction over GSK
5 plc, I find that the allegation of the involvement in the
6 website and so forth is sufficient at this very early juncture
7 to establish -- to deny the motion for dismissal on the grounds
8 of personal jurisdiction and, of course, will leave that open
9 as facts proceed -- factual discovery to proceed at some point.
10 You may look at that again.

11 But at this point I think it's sufficient for
12 plaintiffs to proceed, at least to get more information about
13 the various -- the corporate structure.

14 Concerning plaintiff's claims being barred by the FDA
15 CDC's primary jurisdiction question, I recognize the defendant
16 properly cites to Second Circuit cases finding that reliance on
17 the doctrine of primary jurisdiction is appropriate whenever
18 enforcement of the claim requires resolutions of issues which
19 under regulatory scheme have been placed within the special
20 competence and administrative body, citing of course *Doe v.*
21 *Merck and Company*, (indiscernible) 559. But that was a very
22 different situation. That was a challenge to the FDA's grant
23 of a license.

24 Here I believe, based on my reading of the complaint
25 and the discussion with counsel, this is a false advertising

1 claim. And false advertising claims can and have been
2 (indiscernible) and CDC's primary jurisdiction over safety and
3 efficacy matters.

4 And I will cite here *Jovel v. i-Health, Inc.*, which
5 is 2013 Westlaw 5437065, which is an EDNY case from 2013 which
6 states in fields traditionally occupied by the state such as
7 health and safety regulations, there's a strong presumption
8 against federal preemption claims that a defendant
9 misrepresented the effectiveness of its product and it's
10 traditional claim of misrepresentation, not an attempt to
11 enforce the FDCA's labeling requirement.

12 Federal law constitutes only a floor upon which the
13 states can build additional protections. The FDCA and state
14 law consumer protection statutes serve complimentary, though
15 somewhat overlapping roles.

16 The FDCA is not focused on the truth or false
17 advertising claims, but it's directed to protecting the public
18 by ensuring that the drugs sold in the marketplace are
19 effective and not misbranded. And that's a quote from *Jovel*.

20 And on the same grounds I find in this case, at least
21 again at this juncture, the primary jurisdiction question is
22 not dispositive.

23 (Indiscernible) goes to the damages portion of this
24 case. The issue of the so called defective immunity claim
25 being preempted by the National Childhood Vaccine Injury Act

1 and the failure to exhaust administrative remedies, I'm denying
2 that motion because -- or denying it as moot is the plaintiff
3 now concedes that she is not claiming any physical or emotional
4 injury. So that disposes of that motion.

5 However, that raises a very interesting question as
6 to what exactly the damages are. And I'm going to direct a
7 briefing schedule and I want the plaintiffs and the defendant
8 to brief that question for me because it I think it's a serious
9 question here, particularly in a case, we we've identified,
10 that the economic injury is attenuated by the payment by an
11 insurance company, if indeed that is the situation here.

12 So I'll need the parties to brief that, as well as an
13 additional state law grounds for dismissal because there was a
14 kitchen sink aspect to these letters where apparently there
15 were lots more grounds and the parties want to argue about the
16 state law claims. And I'm going to direct that that be briefed
17 as well.

18 With that in mind let me ask defendant's counsel how
19 long do you need to prepare and serve such a (indiscernible).

20 MR. COONEY: We can do that in two weeks Your Honor.

21 THE COURT: Two weeks. I like that. Ambitious.
22 Good. Let me go to -- plaintiff's counsel, what do you say?
23 How long to respond?

24 MR. SIRI: I don't know. He's making me look bad for
25 what I had in mind. I would respectfully ask for four weeks,

1 Your Honor.

2 THE COURT: How about I'll give you both three weeks.
3 So I'll give defense counsel three weeks to submit and
4 plaintiff's counsel three weeks to respond and then defendant's
5 counsel, I assume you want some sort of reply?

6 MR. COONEY: Yes, Your Honor. Please.

7 THE COURT: And you want three months for that.
8 That's a joke. That's a joke.

9 MR. COONEY: We could do it a week after we get
10 plaintiff's brief, Your Honor.

11 MR. SIRI: I thought he was going to take two days,
12 Your Honor.

13 THE COURT: Well, either way. It's three weeks,
14 three weeks, and one week. So in about seven weeks.

15 At that point, because if we use the bundling rule
16 here defendant's counsel will file the entire bundled brief
17 motions as such.

18 I think I covered everything, but (indiscernible) a
19 lot in this complicated case and I might have missed something.
20 Is there anything else you need me to address?

21 MR. COONEY: Can I ask a question, Your Honor, and
22 that is on the kind of jurisdictional discovery, jurisdictional
23 issues and recognizing that that might become moot depending on
24 your resolution of the damages question, we have a conference
25 with the magistrate judge next week.

1 Would you want us to focus on trying to work out the
2 jurisdictional discovery issues at that time or how would Your
3 Honor like us to proceed in that regard.

4 THE COURT: Okay. Who is the magistrate judge, by the
5 way?

6 MR. COONEY: Magistrate Judge Shields, I believe.

7 THE COURT: Oh, you are so very lucky. I mean, I was
8 a magistrate judge with her for many years and she's so much
9 better than I was. I mean, she's great. So you're going to
10 have a great experience with that.

11 So I think it makes sense to prioritize that, but I'm
12 going to leave that to her good discretion. All right? So
13 I'll let you lay that out for her and she -- because sometimes
14 (indiscernible). Sometimes it's not a big deal. If you're
15 going a deposition and it's two more questions, who cares. So
16 let's see how that goes. All right.

17 MR. COONEY: Thank you, Your Honor.

18 THE COURT: And what I want to say on that, and I
19 know counsel raised the issue about not serving a party who
20 might not be subject to personal jurisdiction, again, based on
21 what I have today I don't see a reason to grant that motion.
22 So I'm not with you on that score, but here's the thing. We're
23 open for business.

24 Judge Shields and I are here in the courthouse
25 literally today and almost every day. So, you know, to the

1 extent something is difficult and you can't work it out, we're
2 here. So we can deal with it on a sort of go forward basis.
3 All right?

4 MR. COONEY: Yes, Your Honor. Thank you.

5 THE COURT: Okay. Anything else?

6 MR. SIRI: Nothing from plaintiff.

7 THE COURT: Not hearing anything, I will conclude for
8 today. I'll just say counsel, again, you did a great job.
9 Thank you for that. Stay well, wear a mask, wash your hands
10 and we'll talk again. All right?

11 MR. COONEY: Thank you, Your Honor.

12 MR. SIRI: Thank you, Your Honor.

13 THE COURT: Okay. We are adjourned.

14 (Proceedings concluded at 3:00 p.m.)
15

16 I, CHRISTINE FIORE, court-approved transcriber and
17 certified electronic reporter and transcriber, certify that the
18 foregoing is a correct transcript from the official electronic
19 sound recording of the proceedings in the above-entitled
20 matter.

21
22 

23 _____ October 25, 2020

24 Christine Fiore, CERT
25